Remarks

Claims 1 to 19 were pending. By this Amendment, claims 3, 6 to 8, 10, and 11, have been cancelled and claims 1, 4, 9, 12, 14, 16, and 18 have been amended to limit the claims to pharmaceutical compositions comprising crystalline telmisartan sodium salt and hydrochlorothiazide. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 1, 2, 4, 5, 9, and 12 to 19, as amended, are now pending.

The Examiner rejected claims 1 to 19 as allegedly anticipated under 35 U.S.C. § 102(e) and allegedly unpatentable under 35 U.S.C. § 103(a) over Reidel *et al.* (U.S. Patent App. Pub. No. 2004/0259925).

In response, applicant respectfully traverses the rejection and maintains that Reidel *et al.* is not a proper reference under 35 U.S.C. § 102(e) and therefore both rejections should be withdrawn. Attached herewith is a certified translation of the priority document German Application No. 10319450.9, filed April 30, 2003 (equivalent to U.S. Serial No. 60/471,675, filed May 19, 2003, for which priority was also claimed). As discussed previously, the subject matter that is the basis for the rejections of the Examiner was not present in Reidel *et al.* in the priority documents German Application No. DE 10301371.7, filed January 16, 2003, and U.S. Serial No. 60/446,695, filed February 11, 2003. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw these rejections.

The Examiner also rejected claims 1 to 19 as allegedly unpatentable under 35 U.S.C. § 103(a) over Nakatani *et al.* (U.S. Patent App. Pub. No. 2004/010813) in view of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) in further view of Lacourciere *et al.* (American J. Therapeutics 2002, 9(2), pages 111-7).

Applicant respectfully traverses the rejection. A *prima facie* case of obviousness generally requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. *See* M.P.E.P. § 2143.

In making this rejection, the Examiner picks unconnected pieces from the disclosure of each reference to make them construct the predetermined result. It is impermissible, however, to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Hedges*, 228 U.S.P.Q. 685 (Fed. Cir. 1986); *In re Wesslau*, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965). A person of ordinary skill in the art would never have necessarily selected and combined these unconnected pieces of the references to assemble the claimed invention, much less with a reasonable expectation of success. Therefore, the Examiner's assertion that a person skilled in the art would have combined these references in a manner necessarily resulting in the claimed invention is untenable and improperly based on hindsight.

For example, Nakatani *et al.* disclose a formulation of telmisartan and not of its sodium salt. Moreover, Nakatani *et al.* do not focus on combinations with diuretics but simply disclose that the telmisartan formulation taught could also be used in the context of combination products; diuretics are but one example of such combination partners and hydrochlorothiazide just one among many examples of diuretics mentioned. Similarly, Lacourciere *et al.* disclose the use of a fixed dose combination of hydrochlorothiazide with the free acid of telmisartan but not its sodium salt. Telmisartan salts, let alone the sodium salt of telmisartan, are not mentioned in Lacourciere *et al.* Finally, Donsbach *et al.* do not teach combinations of telmisartan, much less a diuretic such as hydrochlorothiazide.

Thus, none of Nakatani *et al.*, Donsbach *et al.*, or Lacourciere *et al.* discloses or suggests pharmaceutical compositions of the crystalline sodium salt of telmisartan and hydrochlorothiazide as required in the instant amended claims. Accordingly, there is not a suggestion or motivation in the references or in the knowledge generally available to one of ordinary skill in the art, to obtain pharmaceutical compositions of the crystalline sodium salt of telmisartan and hydrochlorothiazide, much less with a reasonable expectation of success. In addition, the references, alone or in combination do not teach or suggest all of the claim limitations of the instant amended claims. The commercial MICARDIS® (telmisartan sodium) product contains amorphous telmisartan obtained by spray drying. Nakatani *et al.*,

for example, mentions that crystallinity is not of importance, since amorphous telmisartan sodium is obtained by spray drying. Similarly, Donsbach *et al.* seems to intends to improve the preparation of a pharmaceutical composition comprising spray dried (amorphous) telmisartan by providing a compound which is more soluble than the free base of telmisartan. Thus, Nakatani *et al.* and Donsbach *et al.* teach away from preparing pharmaceutical compositions comprising a crystalline sodium salt of telmisartan, since it is seen as unnecessary and not produced by the spray drying method. Furthermore, Lacourciere *et al.* does not provide what Nakatani *et al.* and Donsbach *et al.* lacks, since it focuses on the use of telmisartan with hydrochlorothiazide, and does not mention a crystalline sodium salt of telmisartan. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

Applicant submits that all the pending claims are allowable and respectfully solicits a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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